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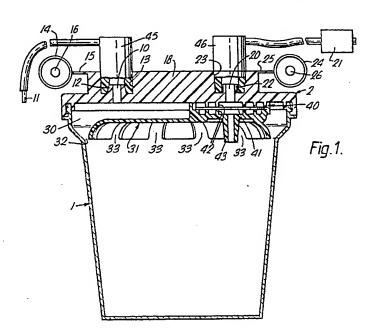
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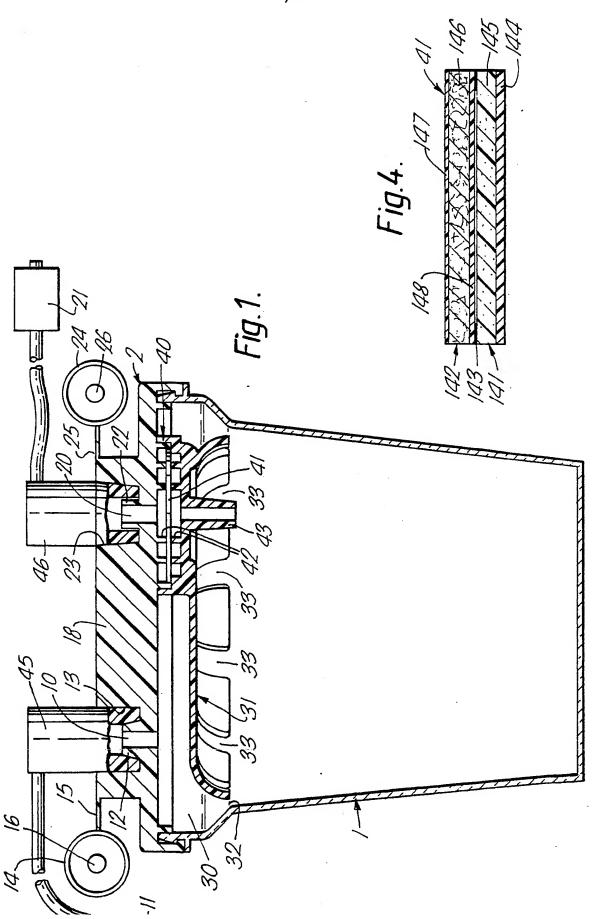
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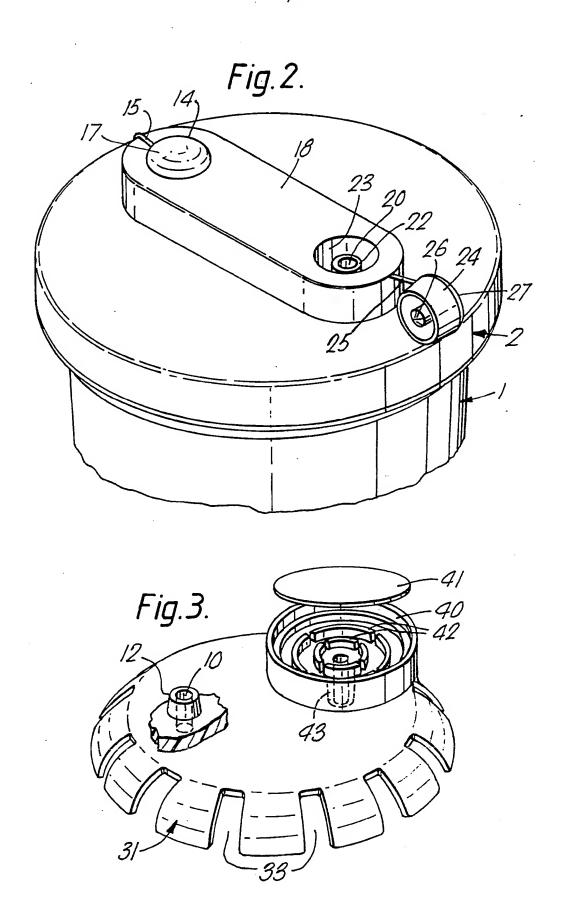
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(54) Medico-surgical containers

(57) A medico-surgical suction container has an inlet 10 connected to a suction catheter 11 and an outlet 20 connected to a pump 21 capable of reducing pressure in the container to at least 500 mm Hg below atmosphere. Within the container, in line with the outlet 20, is a housing 44 containing a filter 41 having a layer of a PTFE membrane on a support screen and a layer of a glass microfibre laminated to a polymer monofilament. The filter 41 allows passage of gas from the container but prevents passage of bacteria and liquid. A tube 43 projects down from the filter housing 44 into the container, the lower end of which defines the maximum filling level, thereby preventing overfilling of the container. The inlet 10 and outlet 20 are formed in recesses 13 and 23 which can be sealed by plugs 14 and 24 attached to the container by flexible webs 15 and 25. The plugs 14 and 24, when inserted, form a smooth surface of the recesses, thereby preventing subsequent removal. An expansion chamber 30 has a convex base plate 31 beneath the inlet 10 so that liquid flows outwardly and down the edge of the plate between a gap 32 with the container and through slots 33 at the edge of the plate.







MEDICO-SURGICAL CONTAINERS AND SUCTION SYSTEMS

This invention relates to medico-surgical containers and suction systems.

The invention is more particularly concerned with containers for collecting liquid and other debris removed from a surgical site by suction in a suction system.

Suction applied by a vacuum pump is used to remove blood, irrigation liquid, tissue debris and the like during surgery. The suction system commonly comprises a suction catheter, a vacuum pump and a collection container. The collection container has two openings one of which is connected to the suction catheter and the other of which is connected to the vacuum pump. The reduced pressure produced by the vacuum pump is communicated with the suction catheter via the container so that material in the surgical site can be sucked along the catheter and collected in the container.

Such collection containers usually have a float-actuated ball valve in the outlet connected to the vacuum pump, the ball valve closing when the liquid in the container rises above a preset level, so as to prevent the liquid being sucked into the vacuum pump. A bacterial filter is often connected between the container and the pump to prevent any airborne or aerosol-borne bacteria being dispersed to the atmosphere.

Because the contents of the collection container after use are often contaminated, their safe disposal presents problems.

It is an object of the present invention to provide an improved medico-surgical container.

According to one aspect of the present invention there is provided a medico-surgical container having an inlet for connection to a suction catheter, an outlet for connection to a vacuum pump, and a filter member located in the container in line with the outlet, the filter member allowing passage of gas from the container to the outlet but preventing passage of bacteria and of liquid such that overfilling of the container is prevented by the filter member.

In this way, the need for a separate float valve and bacterial filter is obviated.

The filter member is preferably contained within a housing having a tube projecting downwardly into the container, the lower end of the tube defining the maximum filling level of the container. The filter member may include a layer comprising a PTFE membrane on a support screen and may include a layer including a glass microfibre laminated to a polymer monofilement.

The container preferably includes plug means for sealing the inlet and outlet after use. The inlet and outlet may be formed in respective recesses, the plug means being shaped such that when inserted they form a smooth surface of the recess making subsequent removal of the plug difficult. The plug means may be each attached to the container by means of a flexible web.

The container preferably includes an expansion chamber located beneath the inlet. The expansion chamber may have a base plate of convex shape arranged such that the liquid from the inlet flows outwardly and down the edge of the plate. The outlet from the expansion chamber is preferably at the edge of the base plate and may include slots formed at the edge of the base plate.

According to another aspect of the present invention there is provided a medico-surgical suction system including a container according to the above one aspect of the invention, a suction catheter connected in communication with the inlet and a vacuum pump connected in communication with the outlet.

The pump is preferably capable of delivering a pressure of at least 500 mm Hg below atmosphere in the container.

A suction system including a suction container in accordance with the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

- Figure 1 is a sectional side elevation view of the container;
- Figure 2 is a perspective view of the top of the container;
- Figure 3 is a perspective view of the interior of the top of the container; and
- Figure 4 is a sectional elevation through the filter member of the container.

With reference first to Figures 1 and 2, the surgical suction system includes a container comprising a cylindrical, transparent jar 1 of a plastics or glass and a top closure 2 that is irremovably sealed to the jar. An inlet 10 and outlet 20 are provided in the top closure 2 that are connected respectively to a suction catheter 11 and a vacuum pump 21 capable of delivering a vacuum of at least 500 mm Hg below atmosphere in the jar 1.

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The inlet 10 and outlet 20 both have a vertical spigot 12 and 22 located within respective cylindrical recesses 13 and 23 formed in a handle 18 that extends across the top of the closure 2. The inlet spigot 12 has a tapered outer surface which mates with a female connector 45 that is connected to the suction catheter 11. The outlet recess 23 is tapered outwardly towards its upper end to receive therein, as a mating fit, a male connector 46 that is connected to the vacuum pump 21. The connectors 45 and 46 are differently shaped and the recesses 13 and 23 are of different diameters so that it is not possible to fit the connectors into the wrong recesses. At opposite ends of the handle 18, plugs 14 and 24 are attached by means of short flexible webs 15 and 25, one of the plugs 14 being shown inserted in Figure 2. One side of each plug 14 and 24 is hollow and formed with a central nose 16 and 26, the external diameter of each plug being such that it is a close, push fit within the recess 13 and 23 with the nose

being a close sealing fit within the respective spigot 12 and 22. The other side of each plug 14 and 24 has a shallow convex surface 17 and 27 respectively. The plugs 14 and 24 can be inserted into their adjacent recess 10 or 20 by bending and twisting their web 15 and 25 so that the convex surface 17 or 27 forms a smooth, shallow projection from the handle which cannot be gripped easily. This prevents the plugs being pulled out readily once inserted.

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The inlet 10 opens into an expansion chamber 30 formed in the top closure 2 and seen most clearly in Figure 3. The chamber 30 has a base plate 31 of convex shape which underlies the inlet 10 so that liquid from the inlet flows outwardly and down the edge of the plate. The diameter of the plate 31 is slightly less than that of the jar 1 so that an annular gap is formed around the outer edge of the plate, between the inner surface of the jar, which provides an outlet from the chamber 30 offset laterally from its inlet 10. Radial slots 33 are spaced around the edge of the plate 31 to provide additional liquid flow paths into the jar. The purposes of the expansion chamber 30 is to reduce turbulence and splashing inside the jar 1 by providing an indirect and smooth flow of liquid from the expansion chamber into the jar.

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The spigot 22 of the vacuum outlet 20 opens into a filter assembly 40 in the top closure 2. The filter assembly 40 has a housing 44 containing a hydrophobic filter element 41 of the kind sold by Arbor Technologies under the trade mark CONTAIN and the code number 85005. The element 41 is shown in more detail in Figure 4 and is a membrane made up of two layers 141 and 142 bonded together around their edge 143. The layer 141 facing the inside of the jar 1 comprises a PTFE membrane 144 laminated with a polypropylene support screen 145, the PTFE membrane facing outwardly. This layer is tested to withstand water breakthrough at at least 10 psi. The layer 142 facing the pump 21 is a glass microfibre 146 which is laminated on both sides with polypropylene monofilament 147 and 148 that is treated to render it hydrophobic. element 41 is retention rated at a particle size of 0.3 micron and can withstand pressure across it of 700 mm Hg. Although different forms of filter element may be effective at removing bacteria at low pressure, at the relatively high pressures encountered in surgical suction systems, a membrane type of element, such as of the kind described, is most effective. The element 41 is supported on both sides by ribs 42 formed internally of the housing 44. On its lower side, the filter assembly 40 communicates with a short vertical vent tube 43 that projects downwardly of the housing 44 into the jar 1 by a short distance, the lower end of the vent tube defining the maximum filling volume of the jar. The element 41 thereby communicates with the jar 1 without the interpositon

of any separate valve or overflow prevention device.

When the pump 21 is turned on, it draws air out of the container through the filter assembly 40 which acts as a bacterial filter to prevent contamination of the pump or atmosphere. The reduced pressure inside the container causes suction to be applied to the suction inlet 10 and hence to the suction catheter 11. This in turn causes any liquid or small debris in the region of the operative tip of the catheter 11 to be sucked along the catheter, through the inlet 10 and the expansion chamber 30 into the container until the level of contents in the jar 1 reaches the lower end of the vent tube 43. When this happens, liquid is drawn up the tube 43 into the filter assembly 40. Although the filter element 41 allows passage of gas, it prevents the passage of liquid, so that the contents of the container are prevented from reaching the vacuum outlet 20. Because further gas flow to the vacuum pump 21 is prevented, suction ceases at the catheter 11, signalling to the user that the container is full. The user then turns off the pump and disconnects the inlet 10 and outlet 20 from their connections, thereby allowing liquid in the filter assembly 40 and tube 43 to flow back down into the jar 1. The plugs 14 and 24 are then pushed into the respective recesses 13 and 23 to seal the jar 1 closed.

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The hydrophobic filter serves the dual function of preventing overfilling and of removing bacteria from gas vented from the container. It avoids the need to provide a separate bacterial filter, thereby simplifying the setting up of the suction system. There is a risk, where a separate bacterial filter is used, that replacement of the filter will be overlooked and that a filter may be left in the system long enough to become damaged. In the present arrangement, because the filter is disposed of every time the collection jar is full, there is less risk of contamination caused by use of a damaged filter. The use of a membrane type filter element enables effective bacterial filtering at the relatively high pressure differentials of about 500 mm Hg encountered in surgical suction systems.

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CLAIMS

- 1. A medico-surgical container having an inlet for connection to a suction catheter, an outlet for connection to a vacuum pump, and a filter member located in said container in line with the outlet, the filter member allowing passage of gas from the container to the outlet but preventing passage of bacteria and of liquid such that overfilling of the container is prevented by said filter member.
- 2. A container according to Claim 1, wherein the filter member is contained within a housing having a tube projecting downwardly into the container, the lower end of the tube defining the maximum filling level of the container.
- 3. A container according to Claim 1 or 2, wherein the filter member includes a layer comprising a PTFE membrane on a support screen.
- 4. A container according to any one of the preceding claims, wherein the filter member includes a layer including a glass microfibre laminated to a polymer monofilament.

- 5. A container according to one of the preceding claims including plug means for sealing the inlet and outlet after use.
- 6. A container according to Claim 5, wherein the inlet and outlet are formed in respective recesses, and wherein the plug means are shaped such that when inserted they form a smooth surface of the recess making subsequent removal of the plug means difficult.
- 7. A container according to Claim 5 or 6, wherein the plug means are each attached to the container by means of a flexible web.
- 8. A container according to any one of the preceding claims, wherein the container includes an expansion chamber located beneath the inlet.
- 9. A container according to Claim 8, wherein the expansion chamber has a base plate of convex shape arranged such that liquid from the inlet flows outwardly and down the edge of the plate.
- 10. A container according to Claim 9, wherein the outlet from the expansion chamber is at the edge of the base plate.

- 11. A container according to Claim 10, wherein the outlet from the expansion chamber includes slots formed at the edge of the base plate.
- 12. A container substantially as hereinbefore described with reference to the accompanying drawings.
- 13. A medico-surgical suction system including a container according to any one of the preceding claims, a suction catheter connected in communication with the inlet and a vacuum pump connected in communication with the outlet.
- 14. A medico-surgical suction system according to Claim 13, wherein the pump is capable of delivering a pressure of at least 500 mm Hg below atmosphere in the container.
- 15. A medico-surgical suction system substantially as hereinbefore described with reference to the accompanying drawings.
- 16. Any novel feature or combination of features as hereinbefore described.

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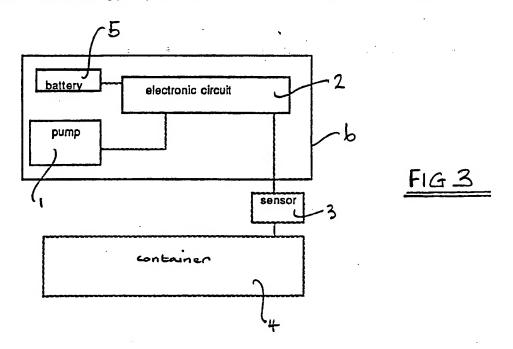
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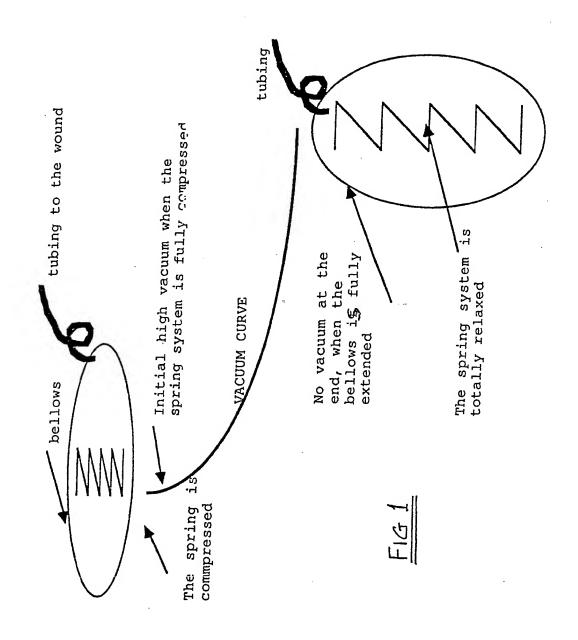
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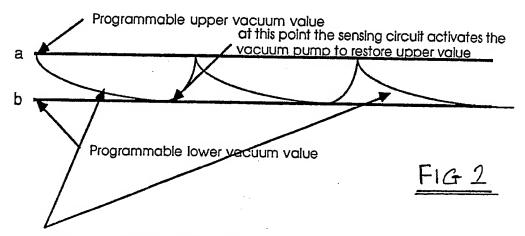
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- (52) UK CL (Edition K) A5R RCE RCW
- (56) Documents cited **GB 1482245 A** GB 2090742 A EP 0128388 A2 EP 0186762 A1
- (58) Field of search UK CL (Edition J) A5R RCE RCW INT CL4 A61M

(54) Closed wound suction apparatus

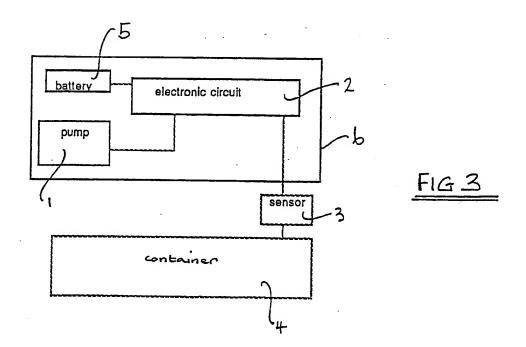
(57) A closed wound suction apparatus comprises a housing, within which there is accommodated a microprocessor controlled battery powered suction pump, and a detachable drainage container arranged to be evacuated by the suction pump so as to apply a suction pressure to a drainage tube embedded in a closed postoperative wound. The suction pressure can be set by the surgeon and is monitored by a pressure sensor which reports to the pump control to determine operation of the pump in accordance with a predetermined set routine. Other controls that can be provided can monitor the volume of exudate in the container and/or the flow rate of exudate into the container. The container is preferably disposable and has self-sealing ports for connection to the vacuum pump and to the drainage tube.

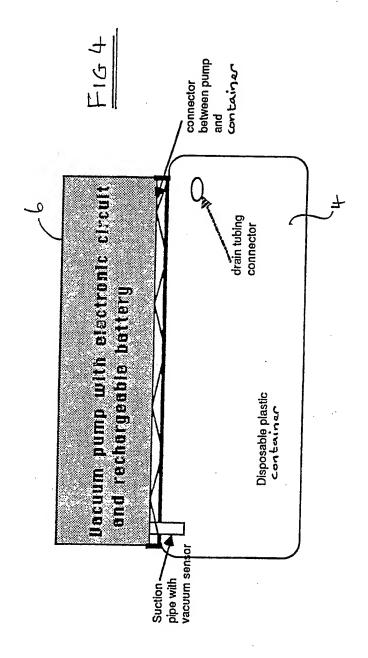






Vacuum curves behaviour, within a pre-programmed working window (a-b)





CLOSED WOUND SUCTION APPARATUS

Field of the Invention:

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This invention concerns improvements in and relating to closed wound suction apparatus for use in effecting proper drainage of a postoperative wound.

Background of the Invention:

Closed wound suction systems are known in which the suction that is applied to a drain tube inserted into a closed wound is achieved by means of a springloaded bellows device which is manually compressed before attachment to the drain tube and develops an internal suction pressure when the manual compression is released and the spring seeks to resile. One such closed wound suction system is the ${\tt MaxiVac^{TM}}$ system that is available from Med General Laboratories Ltd. of Shannon Industrial Estate, Co.Clare, Ireland; this system aids in the maintenance of proper drainage of postoperative accumulation of serosanguineous fluid, purulent material and tissue debris in a wound, and at the same time decreases risk of infection, promotes primary wound healing and promotes the healing process by improving readaptation of tissue layers.

In common with other known closed wound suction

systems utilizing a spring-loaded bellows, the MaxiVacTM system suffers from the disadvantage that the suction that is produced by the bellows is at a maximum when first established and reduces thereafter. This causes uneven drainage of the wound, strong at the beginning and nil subsequently, which can give rise to clogging of the drainage tube. Additionally the vacuum that is generated cannot readily be modulated to the size and extent of the wound.

Objects and Summary of the Invention:

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The principal object of the present invention is the provision of a closed wound suction apparatus which is not susceptible to the abovementioned disadvantages of known systems.

Another object of the present invention is to provide a closed wound suction apparatus enabling the suction pressure to be predetermined and maintained within set limits throughout a drainage period, and advantageously also enabling drainage progress to be monitored.

The above and other objects of the present invention are achieved by provision of a closed wound suction apparatus comprising an electrically operated vacuum pump coupled to a preferably disposable drainage collector coupled in turn to the wound

drainage tube, and wherein means are provided for monitoring and controlling the suction pressure in the drainage collector.

The apparatus according to the invention provides

significant advantages in that the suction applied to
a wound can be set by the surgeon, not only initially
but also subsequently as healing progresses, and will
thereafter be maintained so minimizing the need for
constant progress checking and nurse intervention.

Cost advantages may also be expected in that whilst
the vacuum pump and associated controls are relatively
expensive, the disposable drainage collector may be
significantly less expensive than the bellows devices
of such as the MaxiVacTM aforementioned so that over a

period of time significant cost reductions may result.

The invention will best be understood from consideration of the following detailed description of an exemplary embodiment that is given with reference to the accompanying drawings.

20 Brief Description of the Drawings:

Figure 1 is a schematic showing of the variation in suction pressure that is achieved with a prior art device employing a spring-loaded bellows;

Figure 2 is a schematic showing of the suction pressure obtainable in accordance with the present invention;

Figure 3 is a block diagram showing of an exemplary embodiment of the present invention; and

Figure 4 is a general schematic showing of the embodiment.

5 Detailed Description of the Embodiment:

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As has been explained in the foregoing, Figure 1 shows that the prior art spring-loaded bellows system provides and initial high vacuum level which reduces to zero over a period of time as the spring system of the bellows relaxes. The disadvantages of such prior art systems have been previously explained herein.

Figure 2 shows schematically how a closed wound suction apparatus may be programmed to operate within upper and lower vacuum values, with the electrically operated vacuum pump being switched on when the suction falls to the lower limit and being switched off when the suction rises to the upper limit. The difference between the upper and lower values can be set as desired and can even be reduced to zero or arranged to vary as a function of lapsed time.

Figure 3 is a schematic showing of an embodiment of the invention which comprises a battery operated miniature electric pump 1 coupled to an electronic circuit 2 which is arranged to be responsive to the condition of a pressure sensor 3 for controlling the pump operation within predetermined operator-set

levels. The pump 1 is coupled to a disposable drainage container 4 for determining the suction pressure therein, and the sensor 3 monitors the vacuum in the container 4. The container 4 in use is coupled to the wound drainage tube to receive substances drained from the wound. As shown in Figure 4 the pump 1 and associated electronic circuitry 2 and the battery 5 may be housed in a housing 6 having a suction pipe 7 and arranged to releasably couple with a disposable plastics container 4.

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been previously stated herein, has apparatus according to the invention enables customized vacuum to be set by the surgeon and will then automatically maintain such set vacuum, within predetermined and adjustable limits and optionally for a time period determined by the surgeon or dependent upon the rate of drainage from the wound that is Modern electronics and microprocessor achieved. facilities could if desired be utilized not only for control of the pump but also to monitor other sensors, such as sensors responsive to the quantity of drainage fluid in the container 4 and/or the rate of flow of drainage fluid, and to operate indicators and/or alarms in response thereto. The disposable drainage container 4 will ideally include self-sealing ports for connection to the suction pipe of the apparatus and to the wound drainage tube so as to avoid leakage of possibly hazardous substances from a used drainage container awaiting incineration.

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Monitoring of exudate volume and/or flow rate could be effected in a variety of different ways per se known in the art of liquid volume and flow Non-contact methods are to be preferred for avoidance of risk of cross-contamination which could arise if, for example, re-usable probes were utilized for liquid level sensing. One preferred way of monitoring exudate volume and/or flow rate would be as a function of pump operation; the more frequently the pump has to be operated to maintain a set suction pressure the higher must be the exudate flow rate, and the integrated pump action likewise is an indicator of exudate volume. Where a re-usable drainage container, formed of glass or other autoclavable material for example, was used the exudate level within the container could be monitored by provision of sensor electrodes within the container, for example disposed the container wall, or by optical or other techniques and the flow rate would be proportional to the rate of change of the level. Similar techniques per se known might be incorporated to enable the nature of the exudate to be monitored, for example as a function of its electrical conductivity.

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The present invention thus provides a closed wound suction apparatus whereby a positive and constant suction pressure may be maintained by use of an electronically controlled vacuum pump coupled with an intelligent sensor programmable to the requirements of the particular postoperative condition being treated as determined by the surgeon. By use of microprocessor technology not only can the wound drainage program be set by the surgeon as required, but also the progress of wound drainage can be monitored to monitor exudate volume, flow and/or quality. The exudate container can be disposable and intended only to be used once in which case it should desirably include self-sealing ports, or can be resterilizable and re-usable.

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CLAIMS:

- 1. A closed wound suction apparatus comprising an electrically operated vacuum pump, a drainage container coupled to the pump, a drainage tube coupled to the container and connectable into a wound to be drained, and a pressure sensor responsive to the suction pressure in the container for controlling the pump operation.
- An apparatus as claimed in claim 1 wherein the
 vacuum pump is battery operated.
 - 3. An apparatus as claimed in claim 1 or 2 wherein control means is provided enabling the operating suction pressure of the container to be set by an operator.
- 15 4. An apparatus as claimed in any preceding claim and including one or more further sensors responsive to fluid flow into said container.
 - 5. An apparatus as claimed in any preceding claim wherein the container is disposable.

- 6. An apparatus as claimed in claim 5 wherein the container is self-sealing.
- A closed wound suction apparatus substantially as herein described with reference to Figures 2,3 and 4
 of the accompanying drawings.